China Days

Berlin, Germany

AGENDA

Day 1 – Thusday 11 September 2014

09:00 – 11:00 Registration

11:00 – 11:05 Welcome

11:05 13:00 Doing business in China

- *Christian Goedel (SinaLingua)*
  Cultural awareness: things can be confusing, pitfalls, keeping face, etiquette
- *Yang Liu (Yang Liu Design*)
  East meets West – Yang Liu's personal experience on cultural differences
- Discussion

13:00 – 14:00 Lunch

14:00 – 15:30 Quality systems and Regulatory Processes

- *Jianan Wang (CFDA*)
  Submissions and inspections
- *Andrew Gray (MHRA)*
  Is GLP an appropriate standard for laboratories that analyse samples from human clinical trials? – A European perspective
- *Philip Timmerman (Janssen R&D)*
  Bioanalysis in China: working in the intersection of global regulations and OECD-GLP
- Discussion

15:30 – 16:00 Tea Break

16:00 - 18:00 Bioanalytical Guidelines

- *Daniel Tan (ICON)*
  Introduction
- *Dafang Zhong (Shanghai Institute of Materia Medica)*
  Guideline on bioanalytical method validation in China
- *Daniel Tang (ICON)*
  CBF activities and involvement in guideline conception and review
- Discussion

18:00 – 19:00 Reception

Day 2 – Wednesday 12 September

8:30 – 10:30 Clinical studies

- *Peter van Amsterdam (Abbott Established Pharmaceuticals Division*)
  Introduction to Clinical Trial Applications
- *Pei Hu (Peking Union Medical College Hospital)*
  Early Phase clinical studies

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- *Huafang Li (Shanghai Mental Health Center)*
  Late Phase Clinical Trials
- Discussion

10:30 – 11:00 Coffee Break

11:00 – 12:50 Learning by doing

- *Margarete Brudny-Klöppel (Bayer Pharma AG)*
  How to get the business started
- *Fan Ji (Covance)*
  Operational and Compliance challenges of setting up Bioanalytical Lab in China
- *Johanna Beekman (Bayer Pharma AG)*
  Bayer's experience in sample exportation from China
- *TBD*
  Central lab perspective
- Discussion

12:50 – 13:00 Reflections and Close out

13:00 – 14:00 Lunch